



TESTIMONY OF SHAWN M. BROWN

VICE PRESIDENT OF STATE AFFAIRS

GENERIC PHARMACEUTICAL ASSOCIATION

**“FDA USER FEES 2012: HEARING ON ISSUES RELATED TO
ACCELERATED APPROVAL, MEDICAL GAS, ANTIBIOTIC
DEVELOPMENT AND DOWNSTREAM PHARMACEUTICAL
SUPPLY CHAIN”**

BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

UNITED STATES HOUSE OF REPRESENTATIVES

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Good morning Chairman Pitts, Ranking Member Pallone and Members of the House Energy and Commerce Subcommittee on Health. Thank you for inviting me to testify before the subcommittee on the important topic of securing our nation's pharmaceutical supply chain.

I am Shawn Brown, Vice President of State Affairs at the Generic Pharmaceutical Association. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, bulk pharmaceuticals and suppliers of other goods and services to the generic industry. Generic pharmaceuticals now fill 80 percent of all prescriptions dispensed in the U.S., but account for only 25 percent of the total spending for prescription medicines. According to an analysis by IMS Health, the world's leading data source for pharmaceutical sales, the use of FDA-approved generic drugs in place of their brand counterparts has saved U.S. consumers, patients and the health care system more than \$931 billion over the past decade and \$158 billion in 2010 alone — which equates to \$3 billion in savings every week. The quality and affordability of generic medicines is vital to public health and the sustainability of the health care system.

Introduction

For many years, GPhA has worked closely with multiple stakeholders across the supply chain to ensure that U.S. consumers will continue to benefit from the safest and most secure prescription drug supply in the world. Both industry and the FDA are

exceptionally vigilant against the distribution and sale of counterfeit and adulterated medicines.

Any presence of counterfeit and adulterated pharmaceuticals in our supply chain threatens the integrity of our industry and, more importantly, the health of patients. As the makers of 80 percent of the prescriptions dispensed in the U.S., the generic pharmaceutical industry is deeply committed to ensuring the security of our country's drug supply. GPhA believes that the problem of counterfeit medicines raises a significant public health concern that must be addressed systemically on a range of levels — from local to global, and throughout the drug supply chain.

Our commitment to this issue is further evidenced by the historic Generic Drug User Fee Act currently being considered by the Committee, which recognizes that while providing earlier access to effective medicines is critical — and the key aim of all other existing user fee programs — FDA's central mission is ensuring drug safety. The overall goal of the program is to hold all players, foreign or domestic, contributing to the U.S. generic drug system to the same Good Manufacturing Practices (GMP), and inspection standards, while expediting access to more affordable, high quality generic drugs; the generic drug user fee program will also enhance FDA's ability to identify, track and require the registration of all contributors involved in each generic drug product sold in the U.S.

It is worth noting that low-cost generic drugs are rarely, if ever, targeted by counterfeiters. The primary focus of counterfeiters is on more profitable, and expensive, brand-name products. And in general, as the FDA acknowledges, "counterfeiting is quite rare within the U.S. drug distribution system." GPhA is not aware of a single instance of a counterfeit generic product occurring within the normal chain of distribution in the US. Nevertheless, the generic industry has been a leader in supporting numerous anti-counterfeiting efforts and developing methods to further protect the integrity of the pharmaceutical supply chain. The generic industry is committed to ensuring the safety of the millions of consumers nationwide who use safe, affordable generic medications.

As these efforts move forward, however, it is vital to ensure that any system is practical, focused, and uniform across the country. A uniform system founded on reliable technology and business practices would preclude the unintended consequence of erecting cost barriers to the distribution of safe and effective medicines.

For example, some anti-counterfeiting efforts, such as the drug pedigree model currently set to take effect in 2015 under California law, would require implementation of full electronic "track and trace" capabilities, where the entire distribution history, and the location, of every unit in the supply chain can be determined at any time. The technology to support such a system is unreliable, underdeveloped and the costs associated with such a model would be enormous. Considering the myriad of manufacturers, packaging operations and potential exceptions, this is not a realistic

expectation. Additionally, the California law does not require the Standardized Numerical Identifier (SNI) to be used to verify authenticity, only that there is a pedigree for each number. Drug pedigrees have been forged. An attempt to implement such a system would lead to confusion in the supply chain, aggravate product shortages and dramatically increase costs. Such costly measures would significantly impact the costs for all prescriptions, including low-cost generic medicines.

Previous Efforts to Regulate the Pharmaceutical Supply Chain

As the Committee begins to look closer at this important issue, it is critical to understand how previous efforts at regulating the pharmaceutical supply chain — at both the state and federal level — have led us to where we stand today.

In 1988, Congress passed the Prescription Drug Marketing Act, or PDMA, requiring drugs to be tracked when they passed outside of the normal chain of distribution, which begins at the manufacturer, goes to authorized distributors and finally to the pharmacy. Congress found this necessary because the majority of drugs that were counterfeit, stolen, expired or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute a manufacturer's product. Manufacturers and their authorized distributors were exempted from these requirements, because the introduction of counterfeit medicines would rarely, if ever, occur in this link of the supply chain. However, the law was stayed by the FDA, and finally enjoined in 2006 by a federal district court in New York, in large part because the creation of a national drug

tracking system including all supply chain participants had not been mandated, making the requirements potentially too difficult or impossible to fulfill for many legitimate distributors.

Since that time, this Committee and the Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which directs the FDA to develop standards for the identification, validation, authentication and tracking of prescription drugs, as well as a standard numerical identifier to be applied to a prescription drug at the point of manufacturing and repackaging. While most of these standards have yet to be established, the FDA envisions a full track-and-trace system similar to that in California. However, the FDA concept would require that aggregation of serial numbers — establishing and maintaining that the relationship between unit-level serial numbers with case and pallet serial numbers — be 100 percent accurate. This cannot be achieved. GPhA believes that, in these efforts, perfection has been the enemy of good.

Additional federal legislation has also been introduced in recent years that would urge the establishment of national standards for an electronic tracking system. The legislation pursues the worthy goal of a single, uniform national standard for supply chain security, as opposed to a patchwork of differing state-by-state laws. However, the measures proposed would ultimately require an extensive track-and-trace model for each individual saleable unit of medicine. GPhA believes that adoption of the California model, or one with very similar features, would raise the cost of medicine by billions of dollars over time, would be prone to error, and would have, at best, similar results to the

less-expensive, more efficient model we propose. With billions of units moving quickly and efficiently through the supply chain to fill more than 4 billion prescriptions per year, the magnitude and complexity of such a system is not technically feasible. Indeed, all have underestimated the complexity of the technology requirements and changes in business practices, except those that will use the system every day. Nevertheless, we appreciate the efforts of Members of this Committee to address this important issue and share their goal of ensuring the security of the U.S. pharmaceutical supply chain. Namely, we recognize and appreciate the dedicated attention to this issue given by Congressman Matheson and Congressman Bilbray.

The California law does include language providing for preemption of its requirements in the event that federal legislation is enacted. It is just such an achievement that the Pharmaceutical Distribution Security Alliance (PDSA) hopes this committee will support. With California's initial effectiveness date of 2015 fast approaching, GPhA has helped lead an effort to develop a better approach. In partnership with stakeholders from every area of the pharmaceutical supply chain, we have developed a consensus technological model for increasing the security of the drug supply chain in the U.S. that, we believe, will deliver greater patient safety and help to achieve the FDA's stated goals of preventing the introduction — and facilitating the identification — of counterfeit, diverted, sub-potent, substandard, adulterated, misbranded or expired drugs, providing accountability for the movement of drugs by supply chain participants, and improving the efficiency and effectiveness of recalls. Let me provide some more details.

The PDSA Model

The Pharmaceutical Distribution Security Alliance, or PDSA, is a multi-stakeholder and interdisciplinary initiative whose membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers and pharmacies.

The PDSA's mission is to develop, and help enact, a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients, and to articulate a technical migratory pathway to implement such a policy. Our primary goal is to ensure patients have uninterrupted access to safe, authentic, FDA-approved medicine.

As a member of the PDSA, GPhA strongly supports the Alliance's proposed electronic traceability system known as the Pharmaceutical Traceability Enhancement Code, or RxTEC. This system would increase patient access to safe medicines, while improving the security of our country's drug distribution system. In addition, the RxTEC system would aid state and federal agencies in tracing the distribution history of suspect products, replace the inconsistent and inefficient patchwork of state laws, increase efficiency throughout the drug distribution system and establish foundational technology for future enhancements. The PDSA model is based on technology that we are certain is achievable and scalable.

Specifically, as part of the RxTEC system, manufacturers have committed to serializing individual saleable units of medicine with RxTEC labels, and maintaining and managing RxTEC data in their systems that would associate the serial numbers on individual bottles of medicine with the lot numbers of products. Further, RxTEC peer-to-peer communications would contain the quantity of units associated with the lot. Unit-level serialization provides greater granularity of a lot and improves the visibility of its distribution throughout the supply chain, and also provides unit-level data as an additional check. This system would help identify and prevent the introduction of suspect product through full lot traceability and allow regulatory authorities to validate the serial number of a product at the unit level.

And unlike a full track-and-trace system, which is not technologically feasible in the near term, the RxTEC system would provide immediate measures to increase supply chain security. The system would provide regulators with new authorities and penalties to address counterfeit products, cargo theft, illegal online drug sellers, and new rules regarding e-labeling that will increase patient safety. It would also create more stringent federal standards and state licensing for wholesale distributors, and streamline requirements for manufacturers who also operate as distributors.

To increase the proficiency of the drug distribution system, the RxTEC system would also improve the efficiency and effectiveness of drug recalls and returns, and enable health care providers to leverage technology for record keeping purposes. And in planning for the future, it would provide critical building blocks that can be expanded as

public health threats, interoperability standards and technologies evolve, and establish connectivity and infrastructure throughout the supply chain that will enable a variety of other capabilities and efficiencies.

In short, the RxTEC system is a national supply chain stakeholder consensus model that will replace the patchwork of inconsistent state laws, while increasing patient safety and enhancing our ability to identify and prevent the introduction of suspect product. It is important to recognize the limitations of technology and the necessity of other means of vigilance to address the issues of counterfeiting and diversion of drugs. There is no technology or tracking system that will stop thieves and counterfeiters from attempting to divert products, or profit illegally. However, the PDSA's legislative model represents a landmark improvement in the safety and security of the supply chain, not only through serialization technology to support lot traceability, but also through new stricter licensing requirements, new regulatory authorities, new labeling features and stronger penalties for criminals. We urge the inclusion of the proposal in the user fee package to accomplish these goals.

Conclusion

In conclusion, Mr. Chairman, GPhA and the industry share the concerns of the Committee with regard to maintaining the security of our country's drug supply and preventing the entry of counterfeit, diverted, stolen or other substandard medicines. The development of a uniform, national system is needed to give regulatory authorities

another tool for enforcement, make it more difficult for criminals to breach the supply chain and enhance the ability of the supply chain to respond quickly when a breach has occurred. We believe the RxTEC model proposed by the PDSA achieves all of these goals. Thank you and I would happy to answer any questions you may have.